



## Senate

General Assembly

**File No. 476**

February Session, 2016

Substitute Senate Bill No. 352

*Senate, April 5, 2016*

The Committee on Public Health reported through SEN. GERRATANA of the 6th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

### ***AN ACT CONCERNING PRESCRIPTIONS FOR AND THE DISPENSING OF OPIOID ANTAGONISTS AND OPIOID DRUGS.***

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1      Section 1. (NEW) (*Effective from passage*) (a) A prescribing  
2      practitioner, as defined in section 20-14c of the general statutes, who is  
3      authorized to prescribe an opioid antagonist, as defined in section 17a-  
4      714a of the general statutes, may, by standing order issued to a  
5      pharmacist licensed under part II of chapter 400j of the general  
6      statutes, prescribe an opioid antagonist that is (1) administered by an  
7      intranasal application delivery system or an auto-injection delivery  
8      system, (2) approved by the federal Food and Drug Administration,  
9      and (3) dispensed by the pharmacist to any person at risk of  
10     experiencing an overdose of an opioid drug, as defined in 42 CFR 8.2,  
11     or to a family member, friend or other person in a position to assist a  
12     person at risk of experiencing an overdose of an opioid drug. Any such  
13     prescription shall be regarded as being issued for a legitimate medical  
14     purpose in the usual course of the prescribing practitioner's

15 professional practice. For purposes of this section and section 20-633c  
16 of the general statutes, as amended by this act, "standing order" means  
17 a nonpatient specific prescription for an opioid antagonist that is  
18 administered by an intranasal application delivery system or an auto-  
19 injection delivery system and approved by the federal Food and Drug  
20 Administration.

21 (b) A pharmacist who agrees to accept a standing order issued  
22 under subsection (a) of this section and dispenses an opioid antagonist  
23 in accordance with the provisions of said subsection shall be deemed  
24 not to have violated any standard of care for a pharmacist.

25 Sec. 2. Section 20-633c of the 2016 supplement to the general statutes  
26 is repealed and the following is substituted in lieu thereof (*Effective*  
27 *from passage*):

28 (a) (1) A person who is licensed as a pharmacist under part II of this  
29 chapter and is certified in accordance with subsection (b) of this section  
30 may prescribe, in good faith, an opioid antagonist, as defined in  
31 section 17a-714a. Such pharmacist shall [(1)] (A) provide appropriate  
32 training regarding the administration of such opioid antagonist to the  
33 person to whom the opioid antagonist is dispensed, and [(2)] (B)  
34 maintain a record of such dispensing and the training required  
35 pursuant to this chapter.

36 (2) A person who is licensed as a pharmacist under part II of this  
37 chapter may dispense, in good faith, an opioid antagonist, as defined  
38 in section 17a-714a, that is administered by an intranasal application  
39 delivery system or an auto-injection delivery system, pursuant to a  
40 standing order issued under section 1 of this act.

41 (b) A pharmacist may only prescribe an opioid antagonist pursuant  
42 to this section if the pharmacist has been trained and certified by a  
43 program approved by the Commissioner of Consumer Protection.

44 (c) A pharmacist who prescribes or dispenses an opioid antagonist  
45 in compliance with this section shall be deemed not to have violated

46 any standard of care for a pharmacist.

47 (d) The provisions of subdivision (1) of subsection (a) of this section  
48 shall apply only to a pharmacist certified in accordance with  
49 subsection (b) of this section. No pharmacist may delegate or direct  
50 any other person to (1) prescribe an opioid antagonist, or (2) train any  
51 person in the administration of such opioid antagonist pursuant to the  
52 provisions of subdivision (1) of subsection (a) of this section.

53 (e) The Commissioner of Consumer Protection may adopt  
54 regulations, in accordance with chapter 54, to implement the  
55 provisions of this section.

56 Sec. 3. (NEW) (*Effective from passage*) (a) As used in this section:

57 (1) "Opioid drug" has the same meaning as provided in 42 CFR 8.2;

58 (2) "Adult" means a person who is at least eighteen years of age;

59 (3) "Prescribing practitioner" has the same meaning as provided in  
60 section 20-14c of the general statutes;

61 (4) "Minor" means a person who is under eighteen years of age;

62 (5) "Opioid agonist" means a medication that binds to the opiate  
63 receptors and provides relief to individuals in treatment for abuse of or  
64 dependence on an opioid drug;

65 (6) "Opiate receptor" means a specific site on a cell surface that  
66 interacts in a highly selective fashion with an opioid drug;

67 (7) "Palliative care" means specialized medical care to improve the  
68 quality of life of patients and their families facing the problems  
69 associated with a life-threatening illness; and

70 (8) "Opioid antagonist" has the same meaning as provided in section  
71 17a-714a of the general statutes.

72 (b) When issuing a prescription for an opioid drug to an adult

73 patient for the first time for outpatient use, a prescribing practitioner  
74 who is authorized to prescribe an opioid drug shall not issue a  
75 prescription for more than a seven-day supply of such drug, as  
76 recommended in the National Centers for Disease Control and  
77 Prevention's Guideline for Prescribing Opioids for Chronic Pain.

78 (c) A prescribing practitioner shall not issue a prescription for an  
79 opioid drug to a minor for more than a seven-day supply of such drug  
80 at any time and, when issuing a prescription for an opioid drug to a  
81 minor for less than a seven-day supply of such drug, shall discuss the  
82 risks associated with use of an opioid drug and the reasons why the  
83 prescription is necessary with the custodial parent, guardian or other  
84 person having legal custody of the minor.

85 (d) Notwithstanding the provisions of subsections (b) and (c) of this  
86 section, if, in the professional medical judgment of a prescribing  
87 practitioner, more than a seven-day supply of an opioid drug is  
88 required to treat an adult patient's or minor patient's acute medical  
89 condition, as determined by the prescribing practitioner, or is  
90 necessary for the treatment of chronic pain, pain associated with a  
91 cancer diagnoses or for palliative care, then the prescribing practitioner  
92 may issue a prescription for the quantity needed to treat the acute  
93 medical condition, chronic pain, pain associated with a cancer  
94 diagnosis or pain experienced while the patient is in palliative care.  
95 The condition triggering the prescription of an opioid drug for more  
96 than a seven-day supply shall be documented in the patient's medical  
97 record and the practitioner shall indicate that an alternative to the  
98 opioid drug was not appropriate to address the medical condition.

99 (e) The provisions of subsections (b), (c) and (d) of this section shall  
100 not apply to medications designed for the treatment of abuse of or  
101 dependence on an opioid drug, including, but not limited to, opioid  
102 agonists and opioid antagonists.

<p>This act shall take effect as follows and shall amend the following sections:</p>
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Section 1	<i>from passage</i>	New section
Sec. 2	<i>from passage</i>	20-633c
Sec. 3	<i>from passage</i>	New section

**PH**      *Joint Favorable Subst.*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

***OFA Fiscal Note***

***State Impact:*** None

***Municipal Impact:*** None

***Explanation***

There is no fiscal impact to the state in making changes affecting the prescribing and dispensing of opioid antagonists and opioid drugs as it does not substantially impact procedures at the Department of Consumer Protection.

***The Out Years***

***State Impact:*** None

***Municipal Impact:*** None

**OLR Bill Analysis****sSB 352*****AN ACT CONCERNING PRESCRIPTIONS FOR AND THE DISPENSING OF OPIOID ANTAGONISTS AND OPIOID DRUGS.*****SUMMARY:**

This bill makes changes affecting the prescribing and dispensing of opioid antagonists and opioid drugs. Specifically, it:

1. allows a prescribing practitioner authorized to prescribe an opioid antagonist to issue a standing order (i.e., non-patient specific prescription) to a licensed pharmacist for certain opioid antagonists and
2. prohibits, with certain exceptions, a prescribing practitioner authorized to prescribe an opioid drug from issuing a prescription for more than a seven day supply to (a) an adult for the first time for outpatient use or (b) a minor.

By law, an “opioid antagonist” is naloxone hydrochloride (Narcan) or any other similarly acting and equally safe drug that the FDA has approved for treating a drug overdose.

The bill also makes technical and conforming changes.

EFFECTIVE DATE: Upon passage

**OPIOID ANTAGONIST PRESCRIPTIONS*****Standing Order***

The bill allows a prescribing practitioner authorized to prescribe an opioid antagonist to issue a standing order to a licensed pharmacist for an opioid antagonist that is:

1. administered nasally or by auto-injection;

2. approved by the federal Food and Drug Administration (FDA);  
and
3. dispensed in good faith by the pharmacist to a (a) person at risk of an opioid drug overdose or (b) family member, friend, or other person who may assist a person at risk of such an overdose.

Existing law allows pharmacists to prescribe opioid antagonists if they are trained and certified by the Department of Consumer Protection to do so. When dispensing an opioid antagonist, the pharmacist must train the person on how to administer it. The pharmacist must also keep a record of the dispensing and training under the law's recordkeeping requirements.

### ***Professional Standards of Care***

Under the bill, if a prescribing practitioner issues a standing order for an opioid antagonist, the practitioner is considered to have done so for a legitimate medical purpose in the usual course of his or her professional practice. Additionally, a pharmacist who accepts the standing order and dispenses the opioid antagonist is deemed not to have violated his or her professional standard of care.

## **OPIOID DRUG PRESCRIPTIONS**

### ***Seven-Day Supply***

The bill prohibits a prescribing practitioner authorized to prescribe an opioid drug from issuing a prescription for more than a seven-day supply to (1) an adult for the first time for outpatient use or (2) a minor. When prescribing an opioid drug to a minor, the bill requires the practitioner to discuss with the minor's parent, guardian, or legal custodian the associated risks of using the drug and reasons why the prescription is necessary.

The bill defines an "opioid drug" as any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.



**Exceptions**

The bill allows the practitioner to prescribe more than a seven-day supply to an adult or minor if, in his or her professional judgment, the opioid drug is required to treat the person's medical condition, chronic pain, cancer-associated pain, or for palliative care. The practitioner must document the patient's condition in his or her medical record and indicate that an alternative to the opioid drug was not appropriate to treat the patient's condition.

The bill's provisions regarding opioid drug prescriptions do not apply to medications to treat opioid drug dependence or abuse, including opioid antagonists and agonists (e.g., medications such as morphine that activate the same areas of the brain as other opioids).

**BACKGROUND*****Prescribing Practitioner***

Under existing law, the following health providers may prescribe medication within the scope of their practice: physicians, dentists, podiatrists, optometrists, physician assistants, advanced practice registered nurses, nurse-midwives, and veterinarians (CGS § 20-14c).

***Related Bills***

sSB 353, favorably reported by the Public Health Committee, contains various provisions on opioid abuse prevention and treatment and related issues.

sSB 129, favorably reported by the Public Health and Insurance and Real Estate committees, requires the insurance commissioner to study and report on opioid analgesics and non-abuse deterrent opioid analgesics.

sHB 5053 (File 7), favorably reported by the Public Health and Planning and Development committees, contains various provisions on access to opioid antagonists, such as expanding to any licensed health care professionals existing law's immunity when administering the drug.

HB 5301 (File 143), favorably reported by the Children's Committee, sets requirements for practitioners when prescribing opioids to a minor, including obtaining specific written consent from the parent or guardian.

**COMMITTEE ACTION**

Public Health Committee

Joint Favorable Substitute

Yea    28    Nay   0    (03/21/2016)